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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,035	12/17/1999	MATTI SALLBERG	930049.458C1	9697

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/466,035	SALLBERG ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12,13,24 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12,13,24 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission and the amendment filed on 8/12/04 have been entered. Claims 1-5, 12-13, 24 and 26-30 are pending in the instant application. An action on the merits follows. It is noted that those sections of Title 35, US code not included in this action can be found in the previous office action.

Please note that the examiner of record has changed, see the last page of this office action for details.

Information Disclosure Statement

Applicant's submission of an IDS citing U.S. application no. 08/878,373 on 8/12/04 is acknowledged. However, the copy of the application submitted does not correspond to the specification of 08/878,373. It is suggested that the applicants have made a typographical error and listed the wrong serial number on the 1449. Since the reference provided does not match the application listed on the IDS, the IDS has not been considered. In addition, while the examiner notes that the applicant has requested that the examiner note the prosecution history of "co-

pending application 08/878,373", the application with this serial number is not in fact co-pending with the instant application. The 08/878,373 application issued as U.S. Patent No. 6,148,875 on 11/21/00 and is directed to a vacuum food storage system.

Claim Rejections - 35 USC § 102

The rejection of claims 1-5, 24, and 26-30 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,689,757, hereafter referred to as Craig et al., is withdrawn in view of applicant's amendments to the claims and arguments.

Applicant's amendments to the claims have resulted in the following new grounds of rejection under 35 U.S.C. 102.

Claims 1, 4, 24, 26, and 30 are newly rejected under 35 U.S.C. 102(a) as being anticipated by Fuller et al. (1996) J. Med. Primatol., Vol. 25, 236-241. The applicant claims method of generating an immune response comprising administering to a mammal a plasmid vector encoding at least one immunogenic portion of an antigen derived from an intracellular pathogen and administering to said mammal prior to or subsequent to the administration of the plasmid, at least one protein which comprises an immunogenic portion of an antigen from the intracellular pathogen. The applicant further claims said method wherein the intracellular pathogen is HIV, and wherein the plasmid is naked DNA.

Fuller et al. teaches a prime boost strategy for immunizing a mammal against HIV comprising the administration of a naked DNA plasmid encoding the gag, pol, and env proteins from HIV, followed by the administration of recombinant HIV gp120 envelope protein (Fuller et al., page 237). Fuller et al. further teaches that the increase in antibody responses observed following recombinant subunit boosting demonstrates a synergistic relationship between DNA and recombinant subunit-based vaccines similar to that seen between vaccinia virus and subunit vaccines (Fuller et al., page 240). Thus, by teaching all the elements of the claims as written, Fuller et al. anticipates the instant invention as claimed.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,689,757, hereafter referred to as Craig et al., in view of U.S. Patent No. 5,843,723, hereafter referred to as Dubensky et al., is withdrawn in view of applicant's amendments to the claims and arguments.

Applicant's amendments to the claims have resulted in the following new grounds of rejection under 35 U.S.C. 103(a).

Claims 1-3, 5, 12-13, and 27-29 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/07994 (1995), hereafter referred to as Dubensky et al., in view of Hu

et al. (1991) AIDS Res. Hum. Retrovir., Vol. 7 (7), 615-620. The applicant claims method of generating an immune response comprising administering to a mammal a gene delivery vehicle encoding at least one immunogenic portion of an antigen derived from an intracellular pathogen and administering to said mammal prior to or subsequent to the administration of the gene delivery vehicle, at least one protein which comprises an immunogenic portion of an antigen from the intracellular pathogen. The applicant further claims said method wherein the intracellular pathogen is hepatitis, wherein the gene delivery vehicle is an adeno-associated viral vector, a retroviral vector, or an alphavirus vector, or wherein the gene delivery vehicle is a eukaryotic layered vector initiation system vector. In addition, the applicant claims said method wherein the protein is administered prior to the administration of the gene delivery vehicle.

Dubensky et al. teaches alphavirus vectors and layered eukaryotic vector initiation systems comprising sindbis, retrovirus or adeno-associated virus vectors capable of expressing a heterologous nucleotide sequence (Dubensky et al., pages 8, and 38-40). Dubensky et al. further teaches the administration of alphavirus vector or layered eukaryotic vector initiation systems capable of expressing an antigen to warm-blooded animals in order to generate an antigen-specific immune response (Dubensky et al., pages 33-36, and 40). In particular, Dubensky et al. teaches the generation of immune responses against hepatitis antigens (Dubensky et al., pages 34-35). In addition, Dubensky et al. teaches that immunostimulatory co-factors can be administered with the antigen (Dubensky et al, page 25).

Dubensky et al. differs from the instant invention as claimed by failing to teach a prime-boost strategy of immunization. Hu et al. supplements Dubensky et al. by teaching that

antibody responses against viral antigens can be increased by using a prime boost strategy where a subunit protein vaccine is administered either before or after the administration of a vector encoding the protein antigen (Hu et al., page 615 and page 617, Table 1). The skilled artisan would have been motivated to use the prime-boost strategy taught by Hu et al. to induce immune responses against viral antigens based on the teachings of Hu et al. that boosting vector vaccines with subunit vaccines is more effective than immunization with vector alone. Based on the motivation provided by Hu et al. for using a prime-boost strategy for immunization against viruses, it would have been *prima facie* obvious at the time of filing for the skilled artisan to supplement the immunization strategy using alphavirus vectors and layered eukaryotic initiation systems taught by Dubensky et al. by administering viral proteins prior to or subsequent to the administration of the vector. In view of the enhanced immune response observed by Hu et al. using the prime-boost strategy, the skilled artisan would have had a reasonable expectation of success in generating an immune response against a viral antigen by administering an alphavirus vector or layered eukaryotic initiation system capable of expressing a viral antigen either prior to or subsequent to the administration of viral protein.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's

supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
EXAMINER